JUN 23 2011

K110724

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92.

807.92(a)(1)

Submitter Information

OMNIA SpA
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Date: March 11, 2011

807.92(a)(2)

Trade Name: Omnia Surgical Procedure Packs

Common Name: Surgical Drape Kit

Classification Name(s): Surgical Apparel 878.4040
Surgical Devices 878.4370

Device Classification: II

807.92(a)(3)

Predicate Device

K#	Name	Manufacturer
K041080	Surgical Drape Kit	D.I.R.R.A. srl

Additional substantial equivalence information is provided below.

807.92 (a)(4)

Device Description

Omnia Surgical Procedure Packs are composed of disposable devices, drapes, and surgical garb intended for professional use in preparing the operating environment with protective coverings that aid in maintaining cleanliness and limiting risk of contamination during various types of medical and/or dental surgeries. The contents of these kits may include:

- Surgical Gowns (various models) with or without hand towels
- Sterile Surgical Drapes (various models)
- Face mask
- Protective caps
- Sheath/Tubing Sleeve
- Surgical aspirator with adaptor
- Surgical Gauze
- Sterile disinfection sponge and/or basin
- Adhesive Film
- Syringe (s)
- Needle(s)
- Single-use scalpel
- Small dental mirror/dental explorer/tweezer
- Bone collector
- Saliva ejector
- Irrigation/Infusion line
- Stopcock and ramp for infusion
- Waste bag for contaminated material

807.92(a)(5)

Intended Use(s)

Kit for oral implantology, used by dental professionals when performing surgical procedures.

Indications for Use

Surgical Procedure Packs are composed of disposable devices intended for professional use in preparing the operating environment with protective coverings and clothes that aid in maintaining cleanliness and limiting risk of contamination during various types of medical and/or dental surgeries.

807.92(a)(6)

Summary of Substantial Equivalence

Omnia believes that the Omnia Surgical Procedure Packs are substantially equivalent to the Surgical Drape Kit manufactured by D.I.R.R.A. srl and cleared via 510(k) # K041080. Both devices consist of natural or synthetic materials and are intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial or other contamination. Both devices also include other surgical devices of general utility during various types of medical and/or dental surgeries. Finally, the Omnia Procedure Pack and the predicate device are packaged similarly (single pack in medical envelope) and sterilized via the same sterilization method (ETO).

	Omnia Surgical Procedure Packs	Predicate Device
Trade Name(s)	Surgical Procedure Pack	Surgical Drape Kit
510(k) Number	New	K041080
Manufacturer	Omnia SpA	D.I.R.R.A. srl
Indications for Use	Omnia Surgical Drape Procedure Packs are composed of disposable devices intended for professional use in preparing the operating environment with protective coverings that aid in maintaining cleanliness and limiting risk of contamination during various types of medical and/or dental surgeries.	The D.I.R.R.A. surgical drape device kit is composed of natural or synthetic materials and intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial or other contamination.
Kit Contents	-Surgical gowns (various models) with or without hand towels -Surgical Drapes -Face mask -Protective caps -Sheath/tubing sleeve -Surgical aspirator with adaptor -Surgical gauze -Disinfection sponge -Basin -Adhesive films -Syringe -Needle -Single-use scalpel -Irrigation/infusion line -Stopcock and ramp for infusion -Waste bag for contaminated material -Bone collector -Saliva ejector	-Gown w/ paper towels -Mayo stand cover -Sterile sheet -Patient drape -Transparent drape -Adhesive strip -Tube holder -Cord drape -Suction tubing w/ tip -Flat gauze -Round gauze sponge -Plastic tray -Transparent adhesive film -Connector for suction tubing -Kit wrapping drape
Packaging	Single pack (in medical envelope)	Single pack (in medical envelope)
Sterilization	ETO	ETO

807.92(b)(1)

Summary of Non-Clinical Data

1. **Biocompatibility**
   Biocompatibility was assured via nonclinical testing in accordance with ISO 10993.

2. **Sterilization and Shelf-Life**
   Device sterilization is obtained using ethylene oxide. Sterilization processes were validated in accordance with EN 556 and ISO 11135. Shelf-life has been demonstrated to be a minimum of 5 years after sterilization.

3. **Performance Data**
   Non-clinical performance data for the gowns, masks, and drapes demonstrated conformance to applicable standards (ISO 13795 – ASTM 2407-06 – ASTM 1670-08 – ASTM 1671-07). The characteristics of these items have been previously described in K012186 and K020393 (gowns and drapes) and K911334 (masks).

Conclusion

Based on the testing described above, Omnia has determined that the Omnia Surgical Procedure Packs are substantially equivalent to the Surgical Drape Kit manufactured by D.I.R.R.A. srl (and cleared via 510(k) # K041080) in terms of technology and indications for use. The materials used are biocompatible, the devices are provided sterile with a shelf life of 5 years, and the specifications of the contents of the kit are in accordance with industry standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OMINIA, SpA
c/o Mr. Jamie L. Austin, RAC
Regulatory Consultant
The Anson Group
9001 Wesleyan Road, Suite 200
Indianapolis, Indiana 46268

JUN 23 2011

Re: K110724
Trade/Device Name: Omnia Surgical Procedure Pack
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel; Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: FYA, LRO, KKX & FXX
Dated: June 3, 2011
Received: June 7, 2011

Dear Mr. Austin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 110724

Indications for Use

510(k) Number (if known): / K 110724

Device Name: SURGICAL PROCEDURE PACKS

Indication For Use:

Surgical Procedure Packs are kits for oral implantology, used by dental professionals when performing surgical procedures.

Surgical Procedure Packs are composed of di sposable devices intended for professional use in preparing the operating environment with protective coverings and clothes that aid in maintaining cleanliness and limiting risk of contamination during various types of medical and/or dental surgeries.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Mansie - Wells

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110724